

DECLARATION OF CONFORMITY

1) **Manufacturer** (Name, registered trade name or registered trade mark)

Address: **Brownmed, Inc., 1300 Lundberg Drive West, Spirit Lake, IA 51360, USA**

SRN: US-MF-000008271

2) **European authorized representative:** (Name)

Address: **CEpartner4U BV, Esdoornlaan 13, 3951DB Maarn, The Netherlands**

SRN: NL-AR-000000111

3) **Product(s)** (name, type or model/batch number, etc.)

- | |
|---|
| <ul style="list-style-type: none"> - Cryotherapy and Thermotherapy Devices - Protection Systems - Electroanalgesic Stimulators - Bandages and Splints - Elastic Compression Bandages - Immobilization Bandages for Shoulder, Arm, and Clavicle <p><i>See appendix</i></p> |
|---|

4) **The product(s) described above is in conformity with:**

<u>Title</u>	<u>Document No.</u>
Medical Device Regulation	(EU) 2017/745

5) **Additional information** (conformity procedure, Notified Body, CE certificate, etc.):


Conformity assessment procedure: Medical Device Regulation, Art. 19, Annex II, III and IV

Notified Body and NB-no: N/A CE-certificate nr. : N/A

Registration nr.: N/A

In conformity with following Common Specification(s):

- N/A



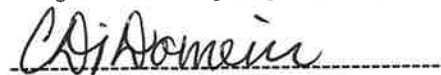
STEPHANIE STEEVES
 Primary Public
 Commonwealth of Massachusetts
 Registration Expires Sept 5, 2025

This Declaration of Conformity is issued under the sole responsibility of the manufacturer:

Boston, USA 2022-11-22

Courteney DiDomenico,

Manager of Product Design, Regulatory Compliance, & Sales Support



(Place & date of issue (yyyy-mm-dd))

(name; function and signature of manufacturer)



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Appendix

Date: 2021-05-18 -

List of devices.

Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
IMAK® Compression	Flex8™ Elbow Brace	Small	61001	ELASTIC COMPRESSION BANDAGES	Class I/rule	0821611IMAKCF8UP	2021-05-18
IMAK® Compression	Flex8™ Elbow Brace	Medium	61002	ELASTIC COMPRESSION BANDAGES	Class I/rule	0821611IMAKCF8UP	2021-05-18
IMAK® Compression	Flex8™ Elbow Brace	Large	61003	ELASTIC COMPRESSION BANDAGES	Class I/rule	0821611IMAKCF8UP	2021-05-18
IMAK® Compression	Flex8™ Elbow Brace	X-Large	61004	ELASTIC COMPRESSION BANDAGES	Class I/rule	0821611IMAKCF8UP	2021-05-18

¹ See risk classification in Medical Device Regulation, annex VIII

² Product and trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device covered by the EU declaration of conformity, such as a photograph, where appropriate, as well as its intended purpose. Except for the product or trade name, the information allowing identification and traceability may be provided by the Basic UDI-DI

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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
IMAK® Compression	Wrist Wrap	Universal	A10302	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMACWWFG	2021-05-18
IMAK® Compression	Neck Support	Universal w/ Gel	A30124	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMAKCNSED	2021-05-18
IMAK® Compression	SHIN SLEEVE™	Small - Black	51054	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161IMAKCSSXJ	2021-05-18
IMAK® Compression	SHIN SLEEVE™	Medium - Black	51055	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161IMAKCSSXJ	2021-05-18
IMAK® Compression	SHIN SLEEVE™	Large - Black	51056	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161IMAKCSSXJ	2021-05-18
IMAK® Compression	SHIN SLEEVE™	X-Large - Black	51057	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161IMAKCSSXJ	2021-05-18
IMAK® Compression	Arthritis Socks	Small	A20190	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMAKCASD6	2021-05-18



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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
IMAK® Compression	Arthritis Socks	Medium	A20191	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMAKCASD6	2021-05-18
IMAK® Compression	Arthritis Socks	Large	A20192	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMAKCASD6	2021-05-18
IMAK® Compression	Arthritis Elbow Sleeve	Small	A20155	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMAKCAESFY	2021-05-18
IMAK® Compression	Arthritis Elbow Sleeve	Medium	A20156	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMAKCAESFY	2021-05-18
IMAK® Compression	Arthritis Elbow Sleeve	Large	A20157	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMAKCAESFY	2021-05-18
IMAK® Compression	Arthritis Glove	X- Small	A20173	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMAKCARTGLWL	2021-05-18
IMAK® Compression	Arthritis Glove	Small	A20170	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMAKCARTGLWL	2021-05-18



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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
IMAK® Compression	Arthritis Glove	Medium	A20171	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMAKCARTGLVVL	2021-05-18
IMAK® Compression	Arthritis Glove	Large	A20172	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMAKCARTGLVVL	2021-05-18
IMAK® Compression	Arthritis Glove	X-Large	A20174	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMAKCARTGLVVL	2021-05-18
IMAK® Compression	Arthritis Thumb	Small	A20178	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMAKCATD8	2021-05-18
IMAK® Compression	Arthritis Thumb	Medium	A20179	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMAKCATD8	2021-05-18
IMAK® Compression	Arthritis Thumb	Large	A20180	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMAKCATD8	2021-05-18
IMAK® Compression	Arthritis Wrist	Small	A20130	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMAKCAWDE	2021-05-18

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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
IMAK® Compression	Arthritis Wrist	Medium	A20131	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMAKCAWDE	2021-05-18
IMAK® Compression	Arthritis Wrist	Large	A20132	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMAKCAWDE	2021-05-18
IMAK® Compression	Active Glove	Small	A20185	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMAKCACTGLVQF	2021-05-18
IMAK® Compression	Active Glove	Medium	A20186	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMAKCACTGLVQF	2021-05-18
IMAK® Compression	Active Glove	Large	A20187	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMAKCACTGLVQF	2021-05-18
IMAK® Compression	Eye Pillow	Universal Retail Box	A30131	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMAKEPDA	2021-05-18
IMAK® Compression	Arthritis Knee	X-Small	A20149	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMAKCAKCN	2021-05-18



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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
IMAK® Compression	Arthritis Knee	Small	A20150	ELASTIC COMPRESSION BANDAGES	Class I/rule	6498331MAKCAKCN	2021-05-18
IMAK® Compression	Arthritis Knee	Medium	A20151	ELASTIC COMPRESSION BANDAGES	Class I/rule	6498331MAKCAKCN	2021-05-18
IMAK® Compression	Arthritis Knee	Large	A20152	ELASTIC COMPRESSION BANDAGES	Class I/rule	6498331MAKCAKCN	2021-05-18
IMAK® Compression	Arthritis Knee	X-Large	A20153	ELASTIC COMPRESSION BANDAGES	Class I/rule	6498331MAKCAKCN	2021-05-18
IMAK® Ergo	Stress Balls	Blue	A10129	ELASTIC COMPRESSION BANDAGES	Class I/rule	6498331MAKESBE4	2021-05-18
IMAK® Ergo	Stress Balls	Black	A10130	ELASTIC COMPRESSION BANDAGES	Class I/rule	6498331MAKESBE4	2021-05-18
IMAK® Ergo	Stress Balls	Heather Gray	A10156	ELASTIC COMPRESSION BANDAGES	Class I/rule	6498331MAKESBE4	2021-05-18

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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
IMAK® Ergo	Back Cushion	Universal	A30122	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMAKEBCK	2021-05-18
IMAK® Ergo	HappiNeck Beige	Universal	A30111	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMAKKHNER	2021-05-18
IMAK® Ergo	HappiNeck - Blue	Universal	A30112	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMAKKHNER	2021-05-18
IMAK® RSI	Pil-O-Splint	Universal	A10312	BANDAGES AND SPLINTS	Class I/rule	649833IMAKRPOSNJ	2021-05-18
IMAK® RSI	Pil-O-Splint	Adjustable	A10112	BANDAGES AND SPLINTS	Class I/rule	649833IMAKRPOSNJ	2021-05-18
IMAK® RSI	WRISTIMER®	Small - To 6.5"	60000	BANDAGES AND SPLINTS	Class I/rule	082161IMAKRWT2E	2021-05-18
IMAK® RSI	WRISTIMER®	Medium - 6.5"-7.5"	60010	BANDAGES AND SPLINTS	Class I/rule	082161IMAKRWT2E	2021-05-18
IMAK® RSI	WRISTIMER®	Large - Over 7.5"	60020	BANDAGES AND SPLINTS	Class I/rule	082161IMAKRWT2E	2021-05-18
IMAK® RSI	WRISTIMER PM®	Universal	60500	BANDAGES AND SPLINTS	Class I/rule	082161IMAKRWT2E	2021-05-18

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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
IMAK® RSI	Elbow Band	Universal	A10301	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMAKREBET	2021-05-18
IMAK® RSI	Elbow Support	Universal	A10113	BANDAGES AND SPLINTS	Class I/rule	649833IMAKRESFV	2021-05-18
IMAK® RSI	Elbow Support	X-Large	A10110	BANDAGES AND SPLINTS	Class I/rule	649833IMAKRESFV	2021-05-18
IMAK® RSI	Elbow Support PM	Universal	A10172	BANDAGES AND SPLINTS	Class I/rule	649833IMAKRESPMX6	2021-05-18
IMAK® RSI	Smart Glove	X-Small	A20111	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMAKRSGGF	2021-05-18
IMAK® RSI	Smart Glove	Small	A20125	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMAKRSGGF	2021-05-18
IMAK® RSI	Smart Glove	Medium	A20126	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMAKRSGGF	2021-05-18
IMAK® RSI	Smart Glove	Large	A20127	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMAKRSGGF	2021-05-18



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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
IMAK® RSI	Smart Glove w/ Thumb	Small	A20161	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMAKRSGWTZF	2021-05-18
IMAK® RSI	Smart Glove w/ Thumb	Medium	A20162	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMAKRSGWTZF	2021-05-18
IMAK® RSI	Smart Glove w/ Thumb	Large	A20163	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMAKRSGWTZF	2021-05-18
IMAK® RSI	Smart Glove PM	Universal	A10111	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMAKRSGPMYC	2021-05-18
IMAK® RSI	Computer Glove	Universal	A20128	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMAKRCGEX	2021-05-18
IMAK® RSI	Knee Strap	Universal	A30137	ELASTIC COMPRESSION BANDAGES	Class I/rule	649833IMAKRKSGF	2021-05-18
IMAK® RSI	Arm Sling	Universal	A30140	IMMOBILIZATION BANDAGES FOR SHOULDER, ARM AND CLAVICLE	Class I/rule	649833IMAKRASFH	2021-05-18



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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
IMAK® RSI	Arm Sling Immobilizer	Universal	A30141	IMMOBILIZATION BANDAGES FOR SHOULDER, ARM AND CLAVICLE	Class I/rule	649833IMAKRSIKX	2021-05-18
Intellinetix®	Vibrating Back	Universal	07239	ELECTROANALGESIC STIMULATORS	Class I/rule	082161INTELLIVBACKFV	2021-05-18
Intellinetix®	Vibrating Calf/Shin	Universal	07237	ELECTROANALGESIC STIMULATORS	Class I/rule	082161INTELLIVCS2D	2021-05-18
Intellinetix®	Vibrating Foot/Ankle	Universal	07242	ELECTROANALGESIC STIMULATORS	Class I/rule	082161INTELLIVFAZF	2021-05-18
Intellinetix®	Vibrating Glove	Small	07230	ELECTROANALGESIC STIMULATORS	Class I/rule	082161INTELLIVGJ4	2021-05-18
Intellinetix®	Vibrating Glove	Medium	07231	ELECTROANALGESIC STIMULATORS	Class I/rule	082161INTELLIVGJ4	2021-05-18
Intellinetix®	Vibrating Glove	Large	07232	ELECTROANALGESIC STIMULATORS	Class I/rule	082161INTELLIVGJ4	2021-05-18
Intellinetix®	Vibrating Headach Band	Universal	07238	ELECTROANALGESIC STIMULATORS	Class I/rule	082161INTELLIVHBZP	2021-05-18
Intellinetix®	Vibrating Knee/Elbow	Universal	07235	ELECTROANALGESIC STIMULATORS	Class I/rule	082161INTELLIVKE29	2021-05-18
Intellinetix®	Vibrating Mask	Universal	07236	ELECTROANALGESIC STIMULATORS	Class I/rule	082161INTELLIVMJG	2021-05-18

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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
Intellinetix®	Vibrating Quad/Thigh	Universal	07241	ELECTROANALGESIC STIMULATORS	Class I/rule	082161INTELLIVQT3R	2021-05-18
Intellinetix®	Vibrating Universal Wrap	Universal	07240	ELECTROANALGESIC STIMULATORS	Class I/rule	082161INTELLIVUW4B	2021-05-18
Intellinetix®	Step Sensor	Universal	07105	ELECTROANALGESIC STIMULATORS	Class I/rule	082161INTELLISSJK	2021-05-18
Joslin®	Ultimate Armsling	Toddler/SM Child	J50001	IMMOBILIZATION BANDAGES FOR SHOULDER, ARM AND CLAVICLE	Class I/rule	656480JUASPB	2021-05-18
Joslin®	Ultimate Armsling	Child/Small Adult	J50101	IMMOBILIZATION BANDAGES FOR SHOULDER, ARM AND CLAVICLE	Class I/rule	656480JUASPB	2021-05-18
Joslin®	Ultimate Armsling	Average Adult	J50201	IMMOBILIZATION BANDAGES FOR SHOULDER, ARM AND CLAVICLE	Class I/rule	656480JUASPB	2021-05-18
Joslin®	Ultimate Armsling	PRO-3XL	J50301	IMMOBILIZATION BANDAGES FOR SHOULDER, ARM AND CLAVICLE	Class I/rule	656480JUASPB	2021-05-18



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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
Joslin®	Ultimate Armsling	Goliath	J50401	IMMOBILIZATION BANDAGES FOR SHOULDER, ARM AND CLAVICLE	Class I/rule	656480JUASPB	2021-05-18
Joslin®	ER Sling	Child	J61545	IMMOBILIZATION BANDAGES FOR SHOULDER, ARM AND CLAVICLE	Class I/rule	656480JERSNE	2021-05-18
Joslin®	ER Sling	Adult	J62545	IMMOBILIZATION BANDAGES FOR SHOULDER, ARM AND CLAVICLE	Class I/rule	656480JERSNE	2021-05-18
Joslin®	ER Sling	Triple X	J63545	IMMOBILIZATION BANDAGES FOR SHOULDER, ARM AND CLAVICLE	Class I/rule	656480JERSNE	2021-05-18
Joslin®	Swathe	Child	J50601	IMMOBILIZATION BANDAGES FOR SHOULDER, ARM AND CLAVICLE	Class I/rule	656480JSHN	2021-05-18



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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
Joslin®	Swathe	Adult	J50501	IMMOBILIZATION BANDAGES FOR SHOULDER, ARM AND CLAVICLE	Class I/rule	656480JSHN	2021-05-18
Joslin®	Swathe	Goliath	J50701	IMMOBILIZATION BANDAGES FOR SHOULDER, ARM AND CLAVICLE	Class I/rule	656480JSHN	2021-05-18
Joslin®	Combo	Adult Regular	J00711	IMMOBILIZATION BANDAGES FOR SHOULDER, ARM AND CLAVICLE	Class I/rule	656480JCGN	2021-05-18
Joslin®	Combo	Adult Large	J00712	IMMOBILIZATION BANDAGES FOR SHOULDER, ARM AND CLAVICLE	Class I/rule	656480JCGN	2021-05-18
NICE STRETCH®	Plantar Fasciitis Night Splint	Universal	A50320	BANDAGES AND SPLINTS	Class I/rule	081261NSPFNS6Z	2021-05-18
NICE STRETCH®	X Lite	Universal	50320	BANDAGES AND SPLINTS	Class I/rule	081261NSXLHT	2021-05-18
NICE STRETCH®	90	Small/Medium	50310	BANDAGES AND SPLINTS	Class I/rule	081261NS90DB	2021-05-18

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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
NICE STRETCH®	90	Large/X-Large	50311	BANDAGES AND SPLINTS	Class I/rule	081261NS90DB	2021-05-18
NICE STRETCH®	Original	Small	51000	BANDAGES AND SPLINTS	Class I/rule	081261NSOUQ	2021-05-18
NICE STRETCH®	Original	Medium	51001	BANDAGES AND SPLINTS	Class I/rule	081261NSOUQ	2021-05-18
NICE STRETCH®	Original	Large	51002	BANDAGES AND SPLINTS	Class I/rule	081261NSOUQ	2021-05-18
NICE STRETCH®	Original	X-Large	51003	BANDAGES AND SPLINTS	Class I/rule	081261NSOUQ	2021-05-18
NICE STRETCH®	PF Sleeve	Small/Medium	53100	ELASTIC COMPRESSION BANDAGES	Class I/rule	081261NSPFSAE	2021-05-18
NICE STRETCH®	PF Sleeve	Large/X-Large	53101	ELASTIC COMPRESSION BANDAGES	Class I/rule	081261NSPFSAE	2021-05-18
NICE STRETCH®	PF Kit	Small/Medium	53104	ELASTIC COMPRESSION BANDAGES	Class I/rule	081261NSPFK9W	2021-05-18
NICE STRETCH®	PF Kit	Large/X-Large	53105	ELASTIC COMPRESSION BANDAGES	Class I/rule	081261NSPFK9W	2021-05-18

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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
NICE STRETCH®	X	Small in bag	51020	BANDAGES AND SPLINTS	Class I/rule	081261NSXVA	2021-05-18
NICE STRETCH®	X	Medium in bag	51021	BANDAGES AND SPLINTS	Class I/rule	081261NSXVA	2021-05-18
NICE STRETCH®	X	Large in bag	51022	BANDAGES AND SPLINTS	Class I/rule	081261NSXVA	2021-05-18
NICE STRETCH®	X	X-Large in bag	51023	BANDAGES AND SPLINTS	Class I/rule	081261NSXVA	2021-05-18
NICE STRETCH®	X	Small w/ Retail Box	51030	BANDAGES AND SPLINTS	Class I/rule	081261NSXVA	2021-05-18
NICE STRETCH®	X	Medium w/ Retail Box	51031	BANDAGES AND SPLINTS	Class I/rule	081261NSXVA	2021-05-18
NICE STRETCH®	X	Large w/ Retail Box	51032	BANDAGES AND SPLINTS	Class I/rule	081261NSXVA	2021-05-18
NICE STRETCH®	X	X-Large w/ Retail Box	51033	BANDAGES AND SPLINTS	Class I/rule	081261NSXVA	2021-05-18
NICE STRETCH®	DORSAL	S/M	52060	BANDAGES AND SPLINTS	Class I/rule	081261NSDU2	2021-05-18
NICE STRETCH®	DORSAL	L/XL	52061	BANDAGES AND SPLINTS	Class I/rule	081261NSDU2	2021-05-18



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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
PLASTALUME®	PLASTALUME® KITS	Number 27 Digital Kit - 3 each, A-1 thru AB-8	10008	BANDAGES AND SPLINTS	Class I/rule	082161PKCT	2021-05-18
PLASTALUME®	PLASTALUME® KITS	Number 40 Digital Kit - 3 each, plus 13 most popular sizes A-1 thru AB-8	10003	BANDAGES AND SPLINTS	Class I/rule	082161PKCT	2021-05-18
PLASTALUME®	PLASTALUME® KITS	Number 54 Digital Kit - 6 each, A-1 thru AB-8	10004	BANDAGES AND SPLINTS	Class I/rule	082161PKCT	2021-05-18
PLASTALUME®	PLASTALUME® KITS	Number 45 Specialty Kit	10030	BANDAGES AND SPLINTS	Class I/rule	082161PKCT	2021-05-18
PLASTALUME®	PLASTALUME® KITS	Number 30 Stax-Mallet Kit	10020	BANDAGES AND SPLINTS	Class I/rule	082161PKCT	2021-05-18
PLASTALUME®	PLASTALUME® KITS	Number 30 Stax-Mallet Kit - Clear	10021	BANDAGES AND SPLINTS	Class I/rule	082161PKCT	2021-05-18

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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
PLASTALUME®	FINGER SPLINTS-BASEBALLS	Small Blue Foam	11111	BANDAGES AND SPLINTS	Class I/rule	082161PFSBF7	2021-05-18
PLASTALUME®	FINGER SPLINTS-BASEBALLS	Medium Blue Foam	11121	BANDAGES AND SPLINTS	Class I/rule	082161PFSBF7	2021-05-18
PLASTALUME®	FINGER SPLINTS-BASEBALLS	Large Blue Foam	11131	BANDAGES AND SPLINTS	Class I/rule	082161PFSBF7	2021-05-18
PLASTALUME®	FINGER SPLINTS-COTS	X Small Blue Foam	10901	BANDAGES AND SPLINTS	Class I/rule	082161PFSBF7	2021-05-18
PLASTALUME®	FINGER SPLINTS-COTS	Small Blue Foam	10911	BANDAGES AND SPLINTS	Class I/rule	082161PFSBF7	2021-05-18
PLASTALUME®	FINGER SPLINTS-COTS	Medium Blue Foam	10921	BANDAGES AND SPLINTS	Class I/rule	082161PFSBF7	2021-05-18
PLASTALUME®	FINGER SPLINTS-COTS	Large Blue Foam	10931	BANDAGES AND SPLINTS	Class I/rule	082161PFSBF7	2021-05-18
PLASTALUME®	FINGER SPLINTS-FROGS	Small Blue Foam	10801	BANDAGES AND SPLINTS	Class I/rule	082161PFSFFF	2021-05-18
PLASTALUME®	FINGER SPLINTS-FROGS	Medium Blue Foam	10811	BANDAGES AND SPLINTS	Class I/rule	082161PFSFFF	2021-05-18
PLASTALUME®	FINGER SPLINTS-FROGS	Large Blue Foam	10821	BANDAGES AND SPLINTS	Class I/rule	082161PFSFFF	2021-05-18

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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
PLASTALUME®	FINGER SPLINTS-PROTECTORS	Small Blue Foam	10501	BANDAGES AND SPLINTS	Class I/rule	082161PFSPG3	2021-05-18
PLASTALUME®	FINGER SPLINTS-PROTECTORS	Medium Blue Foam	10511	BANDAGES AND SPLINTS	Class I/rule	082161PFSPG3	2021-05-18
PLASTALUME®	FINGER SPLINTS-PROTECTORS	Large Blue Foam	10521	BANDAGES AND SPLINTS	Class I/rule	082161PFSPG3	2021-05-18
PLASTALUME®	FINGER SPLINTS-SPOONS	Small Blue Foam	11011	BANDAGES AND SPLINTS	Class I/rule	082161PFSSG9	2021-05-18
PLASTALUME®	FINGER SPLINTS-SPOONS	Medium Blue Foam	11021	BANDAGES AND SPLINTS	Class I/rule	082161PFSSG9	2021-05-18
PLASTALUME®	FINGER SPLINTS-SPOONS	Large Blue Foam	11031	BANDAGES AND SPLINTS	Class I/rule	082161PFSSG9	2021-05-18
PLASTALUME®	FINGER SPLINTS-STAX-MALLETS	Stax 1 Flesh	10701	BANDAGES AND SPLINTS	Class I/rule	082161PFSSM9P	2021-05-18
PLASTALUME®	FINGER SPLINTS-STAX-MALLETS	Stax 2 Flesh	10702	BANDAGES AND SPLINTS	Class I/rule	082161PFSSM9P	2021-05-18
PLASTALUME®	FINGER SPLINTS-STAX-MALLETS	Stax 3 Flesh	10703	BANDAGES AND SPLINTS	Class I/rule	082161PFSSM9P	2021-05-18
PLASTALUME®	FINGER SPLINTS-STAX-MALLETS	Stax 4 Flesh	10704	BANDAGES AND SPLINTS	Class I/rule	082161PFSSM9P	2021-05-18

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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
PLASTALUME®	FINGER SPLINTS-STAX-MALLETS	Stax 5 Flesh	10705	BANDAGES AND SPLINTS	Class I/rule	082161PFSSM9P	2021-05-18
PLASTALUME®	FINGER SPLINTS-STAX-MALLETS	Stax 5.5 Flesh	10706	BANDAGES AND SPLINTS	Class I/rule	082161PFSSM9P	2021-05-18
PLASTALUME®	FINGER SPLINTS-STAX-MALLETS	Stax 6 Flesh	10707	BANDAGES AND SPLINTS	Class I/rule	082161PFSSM9P	2021-05-18
PLASTALUME®	FINGER SPLINTS-STAX-MALLETS	Stax 7 Flesh	10708	BANDAGES AND SPLINTS	Class I/rule	082161PFSSM9P	2021-05-18
PLASTALUME®	FINGER SPLINTS-STAX-MALLETS	Stax 1 Clear	10730	BANDAGES AND SPLINTS	Class I/rule	082161PFSSM9P	2021-05-18
PLASTALUME®	FINGER SPLINTS-STAX-MALLETS	Stax 2 Clear	10731	BANDAGES AND SPLINTS	Class I/rule	082161PFSSM9P	2021-05-18
PLASTALUME®	FINGER SPLINTS-STAX-MALLETS	Stax 3 Clear	10732	BANDAGES AND SPLINTS	Class I/rule	082161PFSSM9P	2021-05-18
PLASTALUME®	FINGER SPLINTS-STAX-MALLETS	Stax 4 Clear	10733	BANDAGES AND SPLINTS	Class I/rule	082161PFSSM9P	2021-05-18
PLASTALUME®	FINGER SPLINTS-STAX-MALLETS	Stax 5 Clear	10734	BANDAGES AND SPLINTS	Class I/rule	082161PFSSM9P	2021-05-18
PLASTALUME®	FINGER SPLINTS-STAX-MALLETS	Stax 5.5 Clear	10735	BANDAGES AND SPLINTS	Class I/rule	082161PFSSM9P	2021-05-18

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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
PLASTALUME®	FINGER SPLINTS-STAX-MALLETS	Stax 6 Clear	10736	BANDAGES AND SPLINTS	Class I/rule	082161PFSSM9P	2021-05-18
PLASTALUME®	FINGER SPLINTS-STAX-MALLETS	Stax 7 Clear	10737	BANDAGES AND SPLINTS	Class I/rule	082161PFSSM9P	2021-05-18
PLASTALUME®	STRIPS	1/2" x 18" Blue Foam	10601	BANDAGES AND SPLINTS	Class I/rule	082161PSDB	2021-05-18
PLASTALUME®	STRIPS	1/2" x 18" White Foam	10602	BANDAGES AND SPLINTS	Class I/rule	082161PSDB	2021-05-18
PLASTALUME®	STRIPS	3/4" x 18" Blue Foam	10611	BANDAGES AND SPLINTS	Class I/rule	082161PSDB	2021-05-18
PLASTALUME®	STRIPS	3/4" x 18" White Foam	10612	BANDAGES AND SPLINTS	Class I/rule	082161PSDB	2021-05-18
PLASTALUME®	STRIPS	1" x 18" Blue Foam	10621	BANDAGES AND SPLINTS	Class I/rule	082161PSDB	2021-05-18
PLASTALUME®	STRIPS	1" x 18" White Foam	10622	BANDAGES AND SPLINTS	Class I/rule	082161PSDB	2021-05-18
PLASTALUME®	STRIPS	1.18" X 18" Blue Foam	10623	BANDAGES AND SPLINTS	Class I/rule	082161PSDB	2021-05-18
PLASTALUME®	STRIPS	1.18" x 18" White Foam	10624	BANDAGES AND SPLINTS	Class I/rule	082161PSDB	2021-05-18

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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
PLASTALUME®	STRIPS	1.57" x 18" Blue Foam	10625	BANDAGES AND SPLINTS	Class I/rule	082161PSDB	2021-05-18
PLASTALUME®	STRIPS	1.57" x 18" White Foam	10626	BANDAGES AND SPLINTS	Class I/rule	082161PSDB	2021-05-18
PLASTALUME®	STRIPS	2" x 16" Blue Foam	10631	BANDAGES AND SPLINTS	Class I/rule	082161PSDB	2021-05-18
PLASTALUME®	STRIPS	2" x 16" White Foam	10632	BANDAGES AND SPLINTS	Class I/rule	082161PSDB	2021-05-18
PLASTALUME®	STRIPS	2" x 18" White Foam	10635	BANDAGES AND SPLINTS	Class I/rule	082161PSDB	2021-05-18
PLASTALUME®	STRIPS	3" x 16" Blue Foam	10641	BANDAGES AND SPLINTS	Class I/rule	082161PSDB	2021-05-18
PLASTALUME®	STRIPS	3" x 16" White Foam	10642	BANDAGES AND SPLINTS	Class I/rule	082161PSDB	2021-05-18
PLASTALUME®	STRIPS	4" x 16" Blue Foam	10651	BANDAGES AND SPLINTS	Class I/rule	082161PSDB	2021-05-18
PLASTALUME®	STRIPS	4" x 16" White Foam	10652	BANDAGES AND SPLINTS	Class I/rule	082161PSDB	2021-05-18
PLASTALUME®	STRIPS	1/2" x 9" Blue Foam	10661	BANDAGES AND SPLINTS	Class I/rule	082161PSDB	2021-05-18

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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
PLASTALUME®	STRIPS	1/2" x 9" White Foam	10662	BANDAGES AND SPLINTS	Class I/rule	082161PSDB	2021-05-18
PLASTALUME®	STRIPS	3/4" x 9" Blue Foam	10671	BANDAGES AND SPLINTS	Class I/rule	082161PSDB	2021-05-18
PLASTALUME®	STRIPS	3/4" x 9" White Foam	10672	BANDAGES AND SPLINTS	Class I/rule	082161PSDB	2021-05-18
PLASTALUME®	STRIPS	1" x 9" Blue Foam	10681	BANDAGES AND SPLINTS	Class I/rule	082161PSDB	2021-05-18
PLASTALUME®	STRIPS	1" x 9" White Foam	10682	BANDAGES AND SPLINTS	Class I/rule	082161PSDB	2021-05-18
PLASTALUME®	DIGITALS	A-1 1 1/4" (33mm)	10101	BANDAGES AND SPLINTS	Class I/rule	082161PDCD	2021-05-18
PLASTALUME®	DIGITALS	A-2 2 1/4" (58mm)	10102	BANDAGES AND SPLINTS	Class I/rule	082161PDCD	2021-05-18
PLASTALUME®	DIGITALS	A-3 3 1/4" (83mm)	10103	BANDAGES AND SPLINTS	Class I/rule	082161PDCD	2021-05-18
PLASTALUME®	DIGITALS	A-4 4 1/8" (106mm)	10104	BANDAGES AND SPLINTS	Class I/rule	082161PDCD	2021-05-18
PLASTALUME®	DIGITALS	AB-4 3 1/4" (83mm)	10105	BANDAGES AND SPLINTS	Class I/rule	082161PDCD	2021-05-18

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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
PLASTALUME®	DIGITALS	AB-5 4 1/4" (110mm)	10106	BANDAGES AND SPLINTS	Class I/rule	082161PDCD	2021-05-18
PLASTALUME®	DIGITALS	AB-6 5 1/4" (134mm)	10107	BANDAGES AND SPLINTS	Class I/rule	082161PDCD	2021-05-18
PLASTALUME®	DIGITALS	AB-7 6 1/4" (160mm)	10108	BANDAGES AND SPLINTS	Class I/rule	082161PDCD	2021-05-18
PLASTALUME®	DIGITALS	AB-8 7 1/4" (186mm)	10109	BANDAGES AND SPLINTS	Class I/rule	082161PDCD	2021-05-18
PLASTALUME®	DIGITALS	AB-9 8 5/8" (220mm)	10110	BANDAGES AND SPLINTS	Class I/rule	082161PDCD	2021-05-18
PLASTALUME®	ARMBOARDS	2 1/4" x 3/4"	SP 10410-25	BANDAGES AND SPLINTS	Class I/rule	082161PABSN	2021-05-18
PLASTALUME®	ARMBOARDS	3 1/4" x 3/4"	SP 10415-25	BANDAGES AND SPLINTS	Class I/rule	082161PABSN	2021-05-18
PLASTALUME®	ARMBOARDS	4" x 1"	SP 10411-25	BANDAGES AND SPLINTS	Class I/rule	082161PABSN	2021-05-18
PLASTALUME®	ARMBOARDS	4 1/2" x 1 1/2"	SP 10414-25	BANDAGES AND SPLINTS	Class I/rule	082161PABSN	2021-05-18
PLASTALUME®	ARMBOARDS	6" x 1 1/2"	SP 10416-25	BANDAGES AND SPLINTS	Class I/rule	082161PABSN	2021-05-18

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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
PLASTALUME®	ARMBOARDS	8" x 2 1/8"	SP 10417-25	BANDAGES AND SPLINTS	Class I/rule	082161PABSN	2021-05-18
PLASTALUME®	ARMBOARDS	10" x 2 1/4"	SP 10418-25	BANDAGES AND SPLINTS	Class I/rule	082161PABSN	2021-05-18
PLASTALUME®	ARMBOARDS w/ Stockinette	2 3/4" x 1"	SP 10452-25	BANDAGES AND SPLINTS	Class I/rule	082161PABWS6P	2021-05-18
PLASTALUME®	ARMBOARDS w/ Stockinette	4" x 1"	SP 10431-25	BANDAGES AND SPLINTS	Class I/rule	082161PABWS6P	2021-05-18
PLASTALUME®	ARMBOARDS w/ Stockinette	4 1/2" x 1 1/2"	SP 10434-25	BANDAGES AND SPLINTS	Class I/rule	082161PABWS6P	2021-05-18
PLASTALUME®	ARMBOARDS w/ Stockinette	6" x 1 1/2"	SP 10436-25	BANDAGES AND SPLINTS	Class I/rule	082161PABWS6P	2021-05-18
PLASTALUME®	ARMBOARDS w/ Stockinette	8" x 2 1/8"	SP 10437-25	BANDAGES AND SPLINTS	Class I/rule	082161PABWS6P	2021-05-18
PLASTALUME®	ARMBOARDS w/ Stockinette	10" x 2 1/4"	SP 10438-25	BANDAGES AND SPLINTS	Class I/rule	082161PABWS6P	2021-05-18
PLASTALUME®	ARMBOARDS PETG w/ Stockinette	4" x 1"	SP 10441-25	BANDAGES AND SPLINTS	Class I/rule	082161PABPWSZ3	2021-05-18
PLASTALUME®	ARMBOARDS PETG w/ Stockinette	4 1/2" x 1 1/2"	SP 10444-25	BANDAGES AND SPLINTS	Class I/rule	082161PABPWSZ3	2021-05-18



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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
PLASTALUME®	ARMBOARDS PETG w/Stockinette	6" x 1 1/2"	SP 10446-25	BANDAGES AND SPLINTS	Class I/rule	082161PABPWSZ3	2021-05-18
PLASTALUME®	ARMBOARDS PETG w/Stockinette	8" x 2 1/8"	SP 10447-25	BANDAGES AND SPLINTS	Class I/rule	082161PABPWSZ3	2021-05-18
PLASTALUME®	ARMBOARDS PETG w/Stockinette	10" x 2 1/4"	SP 10448-25	BANDAGES AND SPLINTS	Class I/rule	082161PABPWSZ3	2021-05-18
PLASTALUME®	Actimove® AluFoam Finger Splint	ACM ALF SPL FISP1.3CMX4 5.7CM 12 INT.	72956-00000-03	BANDAGES AND SPLINTS	Class I/rule	081261PAAFFSVH	2021-05-18
PLASTALUME®	Actimove® AluFoam Finger Splint	ACM ALF SPL FISP 1.9CMX45.7C M 12 INT.	72956-00001-03	BANDAGES AND SPLINTS	Class I/rule	081261PAAFFSVH	2021-05-18
PLASTALUME®	Actimove® AluFoam Finger Splint	ACM ALF SPL FISP 2.5CMX45.7C M 12 INT.	72956-00002-03	BANDAGES AND SPLINTS	Class I/rule	081261PAAFFSVH	2021-05-18
PLASTALUME®	CLASSIC FOREARM SPLINT	Small Right Pad	12111	BANDAGES AND SPLINTS	Class I/rule	082161PCFAS5P	2021-05-18
PLASTALUME®	CLASSIC FOREARM SPLINT	Small Left Pad	12113	BANDAGES AND SPLINTS	Class I/rule	082161PCFAS5P	2021-05-18

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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
PLASTALUME®	CLASSIC FOREARM SPLINT	Medium Right Pad	12121	BANDAGES AND SPLINTS	Class I/rule	082161PCFAS5P	2021-05-18
PLASTALUME®	CLASSIC FOREARM SPLINT	Medium Left Pad	12123	BANDAGES AND SPLINTS	Class I/rule	082161PCFAS5P	2021-05-18
PLASTALUME®	CLASSIC FOREARM SPLINT	Large Right Pad	12131	BANDAGES AND SPLINTS	Class I/rule	082161PCFAS5P	2021-05-18
PLASTALUME®	CLASSIC FOREARM SPLINT	Large Left Pad	12133	BANDAGES AND SPLINTS	Class I/rule	082161PCFAS5P	2021-05-18
PLASTALUME®	POSTERIOR ELBOW SPLINT	Small Pad	13111	BANDAGES AND SPLINTS	Class I/rule	082161PPESGH	2021-05-18
PLASTALUME®	POSTERIOR ELBOW SPLINT	Medium Pad	13121	BANDAGES AND SPLINTS	Class I/rule	082161PPESGH	2021-05-18
PLASTALUME®	POSTERIOR ELBOW SPLINT	Large Pad	13131	BANDAGES AND SPLINTS	Class I/rule	082161PPESGH	2021-05-18
PLASTALUME®	POSTERIOR TIBIA/FIBULA SPLINT	Small 12" Pad W/Foot	15011	BANDAGES AND SPLINTS	Class I/rule	082161PPTFSB7	2021-05-18
PLASTALUME®	POSTERIOR TIBIA/FIBULA SPLINT	Medium 14" Pad W/Foot	15021	BANDAGES AND SPLINTS	Class I/rule	082161PPTFSB7	2021-05-18

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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
PLASTALUME®	POSTERIOR TIBIA/FIBULA SPLINT	Large 16" Pad W/Foot	15031	BANDAGES AND SPLINTS	Class I/rule	082161PPTFSB7	2021-05-18
PLASTALUME®	POSTERIOR FEMUR SPLINT	Small 20" Pad W/Foot	15211	BANDAGES AND SPLINTS	Class I/rule	081261PFSU3	2021-05-18
PLASTALUME®	POSTERIOR FEMUR SPLINT	Medium 25" Pad W/Foot	15221	BANDAGES AND SPLINTS	Class I/rule	081261PFSU3	2021-05-18
PLASTALUME®	POSTERIOR FEMUR SPLINT	Large 31" Pad W/Foot	15231	BANDAGES AND SPLINTS	Class I/rule	081261PFSU3	2021-05-18
PLASTALUME®	COLLES SPLINT	Small Right Pad	12011	BANDAGES AND SPLINTS	Class I/rule	082161PCSTW	2021-05-18
PLASTALUME®	COLLES SPLINT	Small Left Pad	12013	BANDAGES AND SPLINTS	Class I/rule	082161PCSTW	2021-05-18
PLASTALUME®	COLLES SPLINT	Medium Right Pad	12021	BANDAGES AND SPLINTS	Class I/rule	082161PCSTW	2021-05-18
PLASTALUME®	COLLES SPLINT	Medium Left Pad	12023	BANDAGES AND SPLINTS	Class I/rule	082161PCSTW	2021-05-18
PLASTALUME®	COLLES SPLINT	Large Right Pad	12031	BANDAGES AND SPLINTS	Class I/rule	082161PCSTW	2021-05-18
PLASTALUME®	COLLES SPLINT	Large Left Pad	12033	BANDAGES AND SPLINTS	Class I/rule	082161PCSTW	2021-05-18

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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
PLASTALUME®	METACARPAL SPLINT	Small Right Pad	12411	BANDAGES AND SPLINTS	Class I/rule	082161PMSUU	2021-05-18
PLASTALUME®	METACARPAL SPLINT	Small Left Pad	12413	BANDAGES AND SPLINTS	Class I/rule	082161PMSUU	2021-05-18
PLASTALUME®	METACARPAL SPLINT	Medium Right Pad	12421	BANDAGES AND SPLINTS	Class I/rule	082161PMSUU	2021-05-18
PLASTALUME®	METACARPAL SPLINT	Medium Left Pad	12423	BANDAGES AND SPLINTS	Class I/rule	082161PMSUU	2021-05-18
PLASTALUME®	METACARPAL SPLINT	Large Right Pad	12431	BANDAGES AND SPLINTS	Class I/rule	082161PMSUU	2021-05-18
PLASTALUME®	METACARPAL SPLINT	Large Left Pad	12433	BANDAGES AND SPLINTS	Class I/rule	082161PMSUU	2021-05-18
PLASTALUME®	PALM METACARPAL SPLINT	Small Right Pad	12511	BANDAGES AND SPLINTS	Class I/rule	082161PPMSH4	2021-05-18
PLASTALUME®	PALM METACARPAL SPLINT	Small Left Pad	12513	BANDAGES AND SPLINTS	Class I/rule	082161PPMSH4	2021-05-18
PLASTALUME®	PALM METACARPAL SPLINT	Medium Right Pad	12521	BANDAGES AND SPLINTS	Class I/rule	082161PPMSH4	2021-05-18
PLASTALUME®	PALM METACARPAL SPLINT	Medium Left Pad	12523	BANDAGES AND SPLINTS	Class I/rule	082161PPMSH4	2021-05-18



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PLASTALUME®	PALM METACARPAL SPLINT	Large Right Pad	12531	BANDAGES AND SPLINTS	Class I/rule	082161PPMSH4	2021-05-18
PLASTALUME®	PALM METACARPAL SPLINT	Large Left Pad	12533	BANDAGES AND SPLINTS	Class I/rule	082161PPMSH4	2021-05-18
PLASTALUME®	DIGIwrap™	Size 1	10321	BANDAGES AND SPLINTS	Class I/rule	082161PDWU9	2021-05-18
PLASTALUME®	DIGIwrap™	Size 2	10322	BANDAGES AND SPLINTS	Class I/rule	082161PDWU9	2021-05-18
PLASTALUME®	DIGIwrap™	Size 3	10323	BANDAGES AND SPLINTS	Class I/rule	082161PDWU9	2021-05-18
PLASTALUME®	DIGIwrap™	Size 4	10324	BANDAGES AND SPLINTS	Class I/rule	082161PDWU9	2021-05-18
PLASTALUME®	DIGIwrap™	Size 5	10325	BANDAGES AND SPLINTS	Class I/rule	082161PDWU9	2021-05-18
PLASTALUME®	DIGIwrap™	Size 6	10326	BANDAGES AND SPLINTS	Class I/rule	082161PDWU9	2021-05-18
PLASTALUME®	DIGIwrap™	Multi Pack	10327	BANDAGES AND SPLINTS	Class I/rule	082161PDWU9	2021-05-18
PLASTALUME®	DIGIwrap™ TOO	Size 1	10331	BANDAGES AND SPLINTS	Class I/rule	082161PDWTGD	2021-05-18

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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
PLASTALUME®	DIGIwrap™ TOO	Size 2	10332	BANDAGES AND SPLINTS	Class I/rule	082161PDWTGD	2021-05-18
PLASTALUME®	DIGIwrap™ TOO	Size 3	10333	BANDAGES AND SPLINTS	Class I/rule	082161PDWTGD	2021-05-18
PLASTALUME®	DIGIwrap™ TOO	Size 4	10334	BANDAGES AND SPLINTS	Class I/rule	082161PDWTGD	2021-05-18
PLASTALUME®	DIGIwrap™ TOO	Size 5	10335	BANDAGES AND SPLINTS	Class I/rule	082161PDWTGD	2021-05-18
PLASTALUME®	DIGIwrap™ TOO	Size 6	10336	BANDAGES AND SPLINTS	Class I/rule	082161PDWTGD	2021-05-18
PLASTALUME®	DIGIwrap™ TOO	Multi Pack	10337	BANDAGES AND SPLINTS	Class I/rule	082161PDWTGD	2021-05-18
Polar Ice	Finger Sleeve	Small	A10303	CRYOTHERAPY AND THERMOTHERAPY DEVICES	Class I/rule	649833PIFSRE	2021-05-18
Polar Ice	Finger Sleeve	Medium	A10304	CRYOTHERAPY AND THERMOTHERAPY DEVICES	Class I/rule	649833PIFSRE	2021-05-18
Polar Ice	Finger Sleeve	Large	A10305	CRYOTHERAPY AND THERMOTHERAPY DEVICES	Class I/rule	649833PIFSRE	2021-05-18



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Polar Ice™	Shin Ice™	Small	30011	CRYOTHERAPY AND THERMOTHERAPY DEVICES	Class I/rule	082161PISIG4	2021-05-18
Polar Ice™	Shin Ice™	Medium	30012	CRYOTHERAPY AND THERMOTHERAPY DEVICES	Class I/rule	082161PISIG4	2021-05-18
Polar Ice™	Shin Ice™	Large	30013	CRYOTHERAPY AND THERMOTHERAPY DEVICES	Class I/rule	082161PISIG4	2021-05-18
Polar Ice™	Shin Ice™	X-Large	30014	CRYOTHERAPY AND THERMOTHERAPY DEVICES	Class I/rule	082161PISIG4	2021-05-18
Polar Ice™	Polar Ice™	Shoulder/Hip Wrap	30100	CRYOTHERAPY AND THERMOTHERAPY DEVICES	Class I/rule	082161PISHW9X	2021-05-18
Polar Ice™	Polar Ice™	Wrist/Elbow Wrap	30101	CRYOTHERAPY AND THERMOTHERAPY DEVICES	Class I/rule	082161PIWEWAA	2021-05-18
Polar Ice™	Polar Ice™	CPM Knee Wrap	30102	CRYOTHERAPY AND THERMOTHERAPY DEVICES	Class I/rule	082161PICPMKW4K	2021-05-18



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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
Polar Ice™	Polar Ice™	Arthroscopy Knee Wrap Standard	30103	CRYOTHERAPY AND THERMOTHERAPY DEVICES	Class I/rule	082161PIAKW7E	2021-05-18
Polar Ice™	Polar Ice™	Arthroscopy Knee Wrap Large	30104	CRYOTHERAPY AND THERMOTHERAPY DEVICES	Class I/rule	082161PIAKW7E	2021-05-18
Polar Ice™	Polar Ice™	Foot/Ankle Wrap	30105	CRYOTHERAPY AND THERMOTHERAPY DEVICES	Class I/rule	082161PIFAW79	2021-05-18
Polar Ice™	Polar Ice™	Quick Wrap	30107	CRYOTHERAPY AND THERMOTHERAPY DEVICES	Class I/rule	082161PIQWGS	2021-05-18
Polar Ice™	Polar Ice™	Back Wrap	30108	CRYOTHERAPY AND THERMOTHERAPY DEVICES	Class I/rule	082161PIBWFDF	2021-05-18
Polar Ice™	Polar Ice™	TMJ Wrap	30109	CRYOTHERAPY AND THERMOTHERAPY DEVICES	Class I/rule	082161PITMJW6E	2021-05-18
Polar Ice™	Polar Ice™	Hot/Cold Glove Small	31600	CRYOTHERAPY AND THERMOTHERAPY DEVICES	Class I/rule	082161PIPFGFP	2021-05-18



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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
Polar Ice™	Polar Ice™	Hot/Cold Glove Medium	31601	CRYOTHERAPY AND THERMOTHERAPY DEVICES	Class I/rule	082161PIPGFP	2021-05-18
Polar Ice™	Polar Ice™	Hot/Cold Glove Large	31602	CRYOTHERAPY AND THERMOTHERAPY DEVICES	Class I/rule	082161PIPGFP	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Sport-Pediatric (2-10 Years)	Leg	20362	PROTECTION SYSTEMS	Class I/rule	082161STSPPTDX	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Sport-Pediatric (2-10 Years)	Arm	20363	PROTECTION SYSTEMS	Class I/rule	082161STSPPTDX	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Sport-Adult	Short Arm	20320	PROTECTION SYSTEMS	Class I/rule	082161STSPPTDX	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Sport-Adult	Long Arm	20321	PROTECTION SYSTEMS	Class I/rule	082161STSPPTDX	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Sport-Adult	Short Leg	20322	PROTECTION SYSTEMS	Class I/rule	082161STSPPTDX	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Sport-Adult	Long Leg	20323	PROTECTION SYSTEMS	Class I/rule	082161STSPPTDX	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Protector- Knee	Small	20324	PROTECTION SYSTEMS	Class I/rule	082161STPVS	2021-05-18

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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
SEAL-TIGHT®	SEAL-TIGHT® Protector- Knee	Medium	20325	PROTECTION SYSTEMS	Class I/rule	082161STPVS	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Protector- Knee	Large	20326	PROTECTION SYSTEMS	Class I/rule	082161STPVS	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Protector	Small	20318	PROTECTION SYSTEMS	Class I/rule	082161STPVS	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Protector	Medium	20317	PROTECTION SYSTEMS	Class I/rule	082161STPVS	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Protector	Large	20319	PROTECTION SYSTEMS	Class I/rule	082161STPVS	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Original CAST PROTECTORS	Adult Hand	20100	PROTECTION SYSTEMS	Class I/rule	082161STOVQ	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Original CAST PROTECTORS	Adult Short Arm	20101	PROTECTION SYSTEMS	Class I/rule	082161STOVQ	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Original CAST PROTECTORS	Adult Long Arm	20102	PROTECTION SYSTEMS	Class I/rule	082161STOVQ	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Original CAST PROTECTORS	Adult Short Leg	20103	PROTECTION SYSTEMS	Class I/rule	082161STOVQ	2021-05-18



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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
SEAL-TIGHT®	SEAL-TIGHT® Original CAST PROTECTORS	Adult Long Leg	20104	PROTECTION SYSTEMS	Class I/rule	082161STOVQ	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Original CAST PROTECTORS	Foot/Ankle	20105	PROTECTION SYSTEMS	Class I/rule	082161STOVQ	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Original CAST PROTECTORS	Adult Short Leg Wide	20106	PROTECTION SYSTEMS	Class I/rule	082161STOVQ	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Original CAST PROTECTORS	Adult Short Arm Wide	20107	PROTECTION SYSTEMS	Class I/rule	082161STOVQ	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Original CAST PROTECTORS	Pediatric Small Arm	20200	PROTECTION SYSTEMS	Class I/rule	082161STOVQ	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Original CAST PROTECTORS	Pediatric Medium Arm	20201	PROTECTION SYSTEMS	Class I/rule	082161STOVQ	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Original CAST PROTECTORS	Pediatric Large Arm	20202	PROTECTION SYSTEMS	Class I/rule	082161STOVQ	2021-05-18

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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
SEAL-TIGHT®	SEAL-TIGHT® Original CAST PROTECTORS	Pediatric Small Leg	20203	PROTECTION SYSTEMS	Class I/rule	082161STOVQ	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Original CAST PROTECTORS	Pediatric Medium Leg	20204	PROTECTION SYSTEMS	Class I/rule	082161STOVQ	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Original CAST PROTECTORS	Pediatric Large Leg	20205	PROTECTION SYSTEMS	Class I/rule	082161STOVQ	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Original CAST PROTECTORS	16 Piece Pre-pack	20302	PROTECTION SYSTEMS	Class I/rule	082161STOVQ	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Shield	5" x 8"	20435	PROTECTION SYSTEMS	Class I/rule	082161STSHDC7	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Freedom	Adult Arm	26500	PROTECTION SYSTEMS	Class I/rule	082161STFV6	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Freedom	Adult Leg	26501	PROTECTION SYSTEMS	Class I/rule	082161STFV6	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Freedom	Pediatric Arm	26502	PROTECTION SYSTEMS	Class I/rule	082161STFV6	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Freedom	Pediatric Leg	26503	PROTECTION SYSTEMS	Class I/rule	082161STFV6	2021-05-18

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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
SEAL-TIGHT®	SEAL-TIGHT® Freedom	Universal	28002	PROTECTION SYSTEMS	Class I/rule	082161STFV6	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Seal Band	Arm	28075	PROTECTION SYSTEMS	Class I/rule	082161STSBJ2	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Seal Band	Leg	28076	PROTECTION SYSTEMS	Class I/rule	082161STSBJ2	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Infinity	Adult Hand	29400	PROTECTION SYSTEMS	Class I/rule	081261STIV8	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Infinity	Adult Short Arm	29401	PROTECTION SYSTEMS	Class I/rule	081261STIV8	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Infinity	Adult Long Arm	29402	PROTECTION SYSTEMS	Class I/rule	081261STIV8	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Infinity	Adult Wide Short Arm	29407	PROTECTION SYSTEMS	Class I/rule	081261STIV8	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Infinity	Adult Short Leg	29403	PROTECTION SYSTEMS	Class I/rule	081261STIV8	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Infinity	Adult Long Leg	29404	PROTECTION SYSTEMS	Class I/rule	081261STIV8	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Infinity	Adult Foot/Ankle	29405	PROTECTION SYSTEMS	Class I/rule	081261STIV8	2021-05-18

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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
SEAL-TIGHT®	SEAL-TIGHT® Infinity	Adult Wide Short Leg	29406	PROTECTION SYSTEMS	Class I/rule	081261STIV8	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Infinity	Pediatric Small Arm	29408	PROTECTION SYSTEMS	Class I/rule	081261STIV8	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Infinity	Pediatric Medium Arm	29409	PROTECTION SYSTEMS	Class I/rule	081261STIV8	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Infinity	Pediatric Large Arm	29410	PROTECTION SYSTEMS	Class I/rule	081261STIV8	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Infinity	Pediatric Small Leg	29411	PROTECTION SYSTEMS	Class I/rule	081261STIV8	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Infinity	Pediatric Medium Leg	29412	PROTECTION SYSTEMS	Class I/rule	081261STIV8	2021-05-18
SEAL-TIGHT®	SEAL-TIGHT® Infinity	Pediatric Large Leg	29413	PROTECTION SYSTEMS	Class I/rule	081261STIV8	2021-05-18
Soft Stride™	BSP-S Bone Spur Pad	Small	71301	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SOSTBSPDK	2021-05-18
Soft Stride™	BSP-M Bone Spur Pad	Medium	71302	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SOSTBSPDK	2021-05-18



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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
Soft Stride™	BSP-L Bone Spur Pad	Large	71303	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SOSTBSPDK	2021-05-18
Soft Stride™	BSP-S Bone Spur Pad Donut	Small	71501	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SOSTBSPDKJ	2021-05-18
Soft Stride™	BSP-M Bone Spur Pad Donut	Medium	71502	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SOSTBSPDKJ	2021-05-18
Soft Stride™	BSP-L Bone Spur Pad Donut	Large	71503	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SOSTBSPDKJ	2021-05-18
Soft Stride™	EHC-S Extended Heel Cushion	Small	71311	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SOSTEHCC7	2021-05-18
Soft Stride™	EHC-M Extended Heel Cushion	Medium	71312	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SOSTEHCC7	2021-05-18
Soft Stride™	EHC-L Extended Heel Cushion	Large	71313	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SOSTEHCC7	2021-05-18



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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
Soft Stride™	HW-S Heel Wedge	Small	71341	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SOSTHC95	2021-05-18
Soft Stride™	HW-M Heel Wedge	Medium	71342	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SOSTHC95	2021-05-18
Soft Stride™	HW-L Heel Wedge	Large	71343	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SOSTHC95	2021-05-18
Soft Stride™	LAP-S Longitudinal Arch Support Plain	Small	71351	ELASTIC COMPRESSION BANDAGES	Class I/rule	081261SSLASP7N	2021-05-18
Soft Stride™	LAP-M Longitudinal Arch Support Plain	Medium	71352	ELASTIC COMPRESSION BANDAGES	Class I/rule	081261SSLASP7N	2021-05-18
Soft Stride™	LAP-L Longitudinal Arch Support Plain	Large	71353	ELASTIC COMPRESSION BANDAGES	Class I/rule	081261SSLASP7N	2021-05-18
Soft Stride™	LAV-S Longitudinal Arch Support T/C	Small	71356	ELASTIC COMPRESSION BANDAGES	Class I/rule	081261SSLASTCAH	2021-05-18



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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
Soft Stride™	LAV-M Longitudinal Arch Support T/C	Medium	71357	ELASTIC COMPRESSION BANDAGES	Class I/rule	081261SSLASTCAH	2021-05-18
Soft Stride™	LAV-L Longitudinal Arch Support T/C	Large	71358	ELASTIC COMPRESSION BANDAGES	Class I/rule	081261SSLASTCAH	2021-05-18
Soft Stride™	MPP-S Metatarsal Pad Plain	Small	71361	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SOSTMPPEZ	2021-05-18
Soft Stride™	MPP-M Metatarsal Pad Plain	Medium	71362	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SOSTMPPEZ	2021-05-18
Soft Stride™	MPP-L Metatarsal Pad Plain	Large	71363	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SOSTMPPEZ	2021-05-18
Soft Stride™	MPV-S Metatarsal Pad T/C	Small	71366	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SOSTMPVFD	2021-05-18
Soft Stride™	MPV-M Metatarsal Pad T/C	Medium	71367	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SOSTMPVFD	2021-05-18



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Soft Stride™	MPV-L Metatarsal Pad T/C	Large	71368	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SOSTMPVFD	2021-05-18
Soft Stride™	SA-S MultiPad	Small	71371	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SOSTSAA2	2021-05-18
Soft Stride™	SA-M MultiPad	Medium	71372	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SOSTSAA2	2021-05-18
Soft Stride™	SA-L MultiPad	Large	71373	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SOSTSAA2	2021-05-18
Soft Stride™	PW-S Posting Wedge 6/pkg	Small	71381	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SOSTPW5	2021-05-18
Soft Stride™	RDVS-1/4 Sheet Diamond T/C	1/4"	71406	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SOSTRDVSN7	2021-05-18
Soft Stride™	TFP-S Tenderfoot Pad	Small	71411	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SOSTTFPF6	2021-05-18

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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
Soft Stride™	TFP-M Tenderfoot Pad	Medium	71412	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SOSTTFFPF6	2021-05-18
Soft Stride™	TFP-L Tenderfoot Pad	Large	71413	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SOSTTFFPF6	2021-05-18
Soft Stride™	MTI-A Thin Insole T/C	Size A	71421	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SOSTMTIEX	2021-05-18
Soft Stride™	MTI-B Thin Insole T/C	Size B	71422	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SOSTMTIEX	2021-05-18
Soft Stride™	MTI-C Thin Insole T/C	Size C	71423	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SOSTMTIEX	2021-05-18
Soft Stride™	MTI-D Thin Insole T/C	Size D	71424	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SOSTMTIEX	2021-05-18
Soft Stride™	MTI-E Thin Insole T/C	Size E	71425	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SOSTMTIEX	2021-05-18

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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
Spark®	Kinetic Knee Sleeve	Small	40410	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SPARKKKSD9	2021-05-18
Spark®	Kinetic Knee Sleeve	Medium	40411	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SPARKKKSD9	2021-05-18
Spark®	Kinetic Knee Sleeve	Large	40412	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SPARKKKSD9	2021-05-18
Spark®	Kinetic Calf Sleeve	Small	40420	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SPARKKCSCH	2021-05-18
Spark®	Kinetic Calf Sleeve	Medium	40421	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SPARKKCSCH	2021-05-18
Spark®	Kinetic Calf Sleeve	Large	40422	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SPARKKCSCH	2021-05-18
Spark®	Kinetic Ankle Sleeve	Small	40426	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SPARKKASCB	2021-05-18

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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
Spark®	Kinetic Ankle Sleeve	Medium	40427	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SPARKKASCB	2021-05-18
Spark®	Kinetic Ankle Sleeve	Large	40428	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SPARKKASCB	2021-05-18
Spark®	Kinetic Elbow Sleeve	Small	40416	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SPARKKESCP	2021-05-18
Spark®	Kinetic Elbow Sleeve	Medium	40417	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SPARKKESCP	2021-05-18
Spark®	Kinetic Elbow Sleeve	Large	40418	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SPARKKESCP	2021-05-18
Spark®	Kinetic Finger Sleeve	Universal	40430	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161SPARKKFSCS	2021-05-18
STEADY STEP®	HEEL HUGGER™	Small w/Gel	50071	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161STSTHHB6	2021-05-18



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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
STEADY STEP®	HEEL HUGGER™	Medium w/Gel	50072	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161STSTHHB6	2021-05-18
STEADY STEP®	HEEL HUGGER™	Large w/Gel	50073	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161STSTHHB6	2021-05-18
STEADY STEP®	HEEL HUGGER™	X-Large w/Gel	50074	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161STSTHHB6	2021-05-18
STEADY STEP®	HEEL HUGGER™ with Magnets	Small-Gel & Magnets	50161	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161STSTHHWMNZ	2021-05-18
STEADY STEP®	HEEL HUGGER™ with Magnets	Medium-Gel & Magnets	50162	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161STSTHHWMNZ	2021-05-18
STEADY STEP®	HEEL HUGGER™ with Magnets	Large-Gel & Magnets	50163	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161STSTHHWMNZ	2021-05-18
STEADY STEP®	HEEL HUGGER™ with Magnets	X-Large-Gel & Magnets	50164	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161STSTHHWMNZ	2021-05-18

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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
STEADY STEP®	PERFORM 8™	Small Universal	50051	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161STSTP8AY	2021-05-18
STEADY STEP®	PERFORM 8™	Medium Universal	50052	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161STSTP8AY	2021-05-18
STEADY STEP®	PERFORM 8™	Large Universal	50053	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161STSTP8AY	2021-05-18
STEADY STEP®	PERFORM 8™	X-Large Universal	50054	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161STSTP8AY	2021-05-18
STEADY STEP®	TOE HOLD®	Small/Medium Right	50201	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161STSTTHCA	2021-05-18
STEADY STEP®	TOE HOLD®	Small/Medium Left	50202	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161STSTTHCA	2021-05-18
STEADY STEP®	TOE HOLD®	Medium/Large Right	50203	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161STSTTHCA	2021-05-18

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Product name	Trade name	Model	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule ¹	Basic UDI-DI ²	First date of CE-compliance
STEADY STEP®	TOE HOLD®	Medium/Large Left	50204	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161STSTTHCA	2021-05-18
STEADY STEP®	Sol Step™	Small	50040	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161STSTSSCV	2021-05-18
STEADY STEP®	Sol Step™	Medium	50041	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161STSTSSCV	2021-05-18
STEADY STEP®	Sol Step™	Large	50042	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161STSTSSCV	2021-05-18
STEADY STEP®	Sol Step™	XLarge	50043	ELASTIC COMPRESSION BANDAGES	Class I/rule	082161STSTSSCV	2021-05-18
STEADY STEP®	HERBST CRADLE™	Small	04020	BANDAGES AND SPLINTS	Class I/rule	082161STSTHCAU	2021-05-18
STEADY STEP®	HERBST CRADLE™	Medium	04021	BANDAGES AND SPLINTS	Class I/rule	082161STSTHCAU	2021-05-18
STEADY STEP®	HERBST CRADLE™	Large	04022	BANDAGES AND SPLINTS	Class I/rule	082161STSTHCAU	2021-05-18